Supreme Court, U.S.
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No. 93-711

In The

Supreme Court of the United States

October Term, 1993

AMY DeLUCA, an infant by her guardian ad litem, Cindy DeLuca, and Cindy DeLuca and Ronald DeLuca, individually,

Petitioners,

vs.

MERRELL DOW PHARMACEUTICALS, INC., Dr. Patrick J. Dwyer, Dr. Teresa Benecki, Dr. Pieter J. Ketelaar, Dr. Robert E. Sexton, ind. and t/a Pineland Associates,

Respondents.

Petition For Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED FOR REVIEW

Whether the court of appeals, in affirming the district court's holding that proffered expert testimony was unreliable as set forth in its findings of fact and conclusions of law, correctly applied to the particular facts of this case the standard for admissibility of expert testimony set forth in *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 U.S. ___, 113 S. Ct. 2786 (1993).

PARTIES

Merrell Dow Pharmaceuticals Inc. ("Merrell Dow") is a wholly-owned subsidiary of Marion Merrell Dow Inc. as of December 2, 1989. Approximately 70% of the stock of Marion Merrell Dow Inc. is held by the Dow Chemical Company. Both Marion Merrell Dow Inc. and the Dow Chemical Company are publicly held corporations. A complete list of publicly held subsidiary and affiliates follows:

The Dow Chemical Company
Arabian Chemical Company Limited
DCU/LB TRUST
Destec Energy, Inc.
Dexco Polymers
Dow Chemical Iberica S.A.
Chemtech Royalty Associates, L.P.
DowBrands Espanola S.A.
Crestar Energy Inc.
Fort Saskatchewan Ethylene Storage Limited Partnership
H-D Tech Inc.
Cromarty Petroleum Company Limited
Petroquimica-Dow S.A. (Petrodow)
Dow Chemical Japan Limited
Ulsan Pacific Chemical Corporation
Epoxital S.R.L.
Safechem Umwelt Service GmbH
DowBrands L.P.
Dow Corning Corporation
Marion Merrell Dow Inc.
Fort Saskatchewan Ethylene Storage Corporation
Promix System
Dow Kakoh Kabushiki Kaisha

PARTIES – Continued

Dow Mitsubishi Kasei Limited
Dow Quimica Argentina S.A.
Anticorrosivos Industriales Limitada
Dow-United Technologies Composite Products Inc.
El Dorado Terminals Company
Expandite Essex Pty. Limited
Gurit-Essex A.G.
Etoxilados del Plata S.A.
H.D. Polyurethane Company
Joliet Marine Terminal Trust Estate
Lucky Epoxy Limited
Marisub V, Inc.
Carderm Capital L.P.
Marion Merrell Dow K.K.
MDP Holdings Ltd.
P.T. Pacific Indomas Plastic Indonesia
Airco Generon Systems LP
DH Compounding Company
DowElanco
Dong Yang Elanco Co. Ltd.
DowElanco B.V.
Elanco Ihara K.K.
P.T. Pacific Chemicals Indonesia
Generon Systems
Generon Systems A.G.
Sumitomo Dow Limited
Zhejiang Pacific Chemical Corporation

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STATEMENT OF THE CASE

The infant plaintiff, Amy DeLuca, was born with limb reduction defects which plaintiffs allege were due to Mrs. DeLuca's ingestion of the pharmaceutical product Bendectin during pregnancy. On remand, the court held a hearing in accordance with Fed. R. Evid. 104(a). That hearing ultimately extended over five court days. The court took extensive testimony from experts offered by defendant Merrell Dow, including epidemiologists Richard Monson, M.D., Sc.D.; Nicholas Wright, M.D., M.P.H.; Steven H. Lamm, M.D.; and Gerald A. Faich, M.D., M.P.H.; geneticist Pauline Brenholz, M.D.; and biochemist/pharmacologist Paul Stanley Lietman, M.D., Ph.D. Although not limited by the trial court, plaintiffs offered only one witness on the issue of causation, Dr. Alan K. Done, plus a second witness, Dr. Shanna Swan (an epidemiologist), whose role was limited to rendering an opinion on Dr. Done's use of epidemiology. The district court found that Dr. Swan:

> did not independently verify the data included on Dr. Done's chart, did not check his calculations and did not check to see if Dr. Done correctly extracted the data from the articles as to which he made no calculations. Swan Test., Tr. 7/12/91, at 7-14. Dr. Swan merely commented on Dr. Done's methodology as he described it and "took as a given that he did what he said he did." Swan Test., Tr. 7/12/91, at 9-21.

(15a, ¶ 32 footnote omitted.)[1] Given the absence of an independent opinion on causation by Dr. Swan, the district court's inquiry properly focused on the methodology of Dr. Done.

Dr. Done conceded that the authors of the over 30 published studies on Bendectin had concluded that their studies failed to demonstrate an association between Bendectin and limb reduction defects, (13a, ¶ 24), but contended that his reanalysis of the studies according to his own methodology established an association between Bendectin and birth defects, (13a-14a, ¶ 28). The district court found that the methodology used by Dr. Done in making his calculations and presenting his data was not standard epidemiologic methodology, and was so replete with error that it was completely unreliable. The court found that defense experts Dr. Richard Monson, Dr. Nicholas Wright, and Dr. Steven Lamm, as well as plaintiffs' own expert, Dr. Shanna Swan, all testified that they could not replicate Dr. Done's recalculations in many cases, (16a, ¶ 36), and specifically found that:

> Dr. Swan, plaintiffs' epidemiologist and statistician, could not verify the accuracy of Dr. Done's calculations. In addition, she testified that she was frequently unable to determine the precise methodology used by Dr. Done in selecting data to calculate relative risks and confidence intervals, and in actually calculating those intervals.

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[1] All citations in this Statement of the Case are to the Appendix attached to the Petition for Writ of Certiorari.

(38a, ¶ 18.) The court further found that the method used by Dr. Done was not in conformance with any known methodology:

> [t]he defense experts as well as Dr. Swan testified that the precise method used by Dr. Done in making some of his calculations was a mystery and was not in conformance with any known methodology.

(16a, ¶ 35.)

The methodological errors of Dr. Done included calculating relative risks outside of the confidence intervals, (17a, ¶ 37), calculating two different relative risks from the same study, (17a, ¶ 38), inflating certain relative risks, (17a-18a, ¶¶ 40-42; 19a, ¶ 48; 20a, ¶¶ 53, 54), incorporating data not relating to the Bendectin ingested by Mrs. DeLuca, (20a-21a, ¶¶ 56, 59), and treating preliminary drafts as if they were final studies, (21a, ¶¶ 61, 62). Dr. Done also selectively included and excluded data, (24a-25a, ¶¶ 76-83), improperly weighed data, (25a-26a, ¶¶ 84-88), presented confidence intervals in a misleading manner, (27a-28a, ¶¶ 92-97), and made numerous other errors and misstatements on his graphs, worksheets, and charts, (28a-30a, ¶¶ 98-103; 30a-31a, ¶¶ 108-113). The district court accordingly found Dr. Done's methodology to be unreliable under Fed. R. Evid. 702.

The district court also found that Dr. Done relied on data not reasonably relied upon by experts in the field of epidemiology, (22a-23a, ¶¶ 68-75; 42a-44a, ¶¶ 33-38). It therefore also found that Dr. Done's testimony was additionally excludable under Fed. R. Evid. 703.

The case was fully briefed before the Third Circuit Court of Appeals. After briefing was completed, the court of appeals stayed disposition of the matter pending this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals Inc.* After the decision in *Daubert* was issued, *see* 509 U.S. ___, 113 S. Ct. 2786 (1993), the Third Circuit Court of Appeals requested supplemental briefing by the parties on the applicability of the *Daubert* decision to the facts of this case. In subsequently affirming the district court's opinion, the court of appeals noted that it had considered both *Daubert* and the parties' supplemental briefs before rendering its decision. (4a.)

REASONS FOR DENYING WRIT

This Court fully considered and addressed the standards governing the admissibility of scientific evidence in another Bendectin case in a recent opinion issued on June 28, 1993. *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 U.S. ___, 113 S. Ct. 2786 (1993). The Third Circuit's opinion in the instant case specifically states that it considered *Daubert* and the parties' supplemental briefs addressed to that case in affirming the decision of the district court. It is respectfully submitted that plaintiffs have failed to offer the slightest basis for revisiting the same issue of admissibility of scientific evidence in the wake of *Daubert*.

In *Daubert*, this Court held that the Federal Rules of Evidence, rather than the "*Frye* test" or "general acceptance" standard, govern the admissibility of scientific expert testimony. The Court in *Daubert* directed trial

judges to closely scrutinize proffered scientific expert testimony:

> [t]o the contrary, under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.

509 U.S. at ___, 113 S. Ct. at 2795. This Court also noted its confidence in the ability of federal judges to fulfill that responsibility.

> Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. . . . *We are confident the federal judges possess the capacity to undertake this review.*

509 U.S. at ___, 113 S. Ct. at 2796. (footnotes omitted) (emphasis added). In this case the trial court judge and the judges sitting on the court of appeals have demonstrated that this confidence is well placed.

Although plaintiffs' Statement of the Case attempts to create the impression that a legal issue exists by means of a distinction between methodology and Dr. Done's application of methodology, it is clear in this case that this is a distinction without a difference. The methodology that must be found reliable is not what experts *say* they are doing but what they actually do. The concurrent finding of the lower courts in this case was that Dr. Done's actual analysis, riddled with numerous indefensible missteps (as recounted above), bore no recognized

relation to a reliable method of analyzing data for purposes of scientific inference. This is not a case, therefore, involving a legitimate scientific debate between reliable schools of thought about the conclusions that may properly be drawn from experiments, statistics, or other methods of analysis that are themselves accepted as valid. Accordingly, the lower courts' rejection of Dr. Done's testimony as inadmissible, far from crossing the line into areas presenting jury questions, followed precisely the reliability approach contemplated by this Court's interpretation of Fed. R. Evid. 702 in *Daubert*. *See Daubert*, 509 U.S. at ___, 113 S. Ct. at 2797 (focus must be on "principles and methodology, not on the conclusions that they generate").

In sum, the issue presented by the petition is in reality nothing more than a factual inquiry as to whether the record below is sufficient to support the lower court's findings as to the unreliability of plaintiffs' proffered scientific expert testimony. Petitioners seek a review of the evidence in a case where the district court made 120 detailed and specific findings of fact and 41 separate conclusions of law after a five day Rule 104(a) hearing. All three judges on the court of appeals concurred in the affirmance of the district court's decision, and all thirteen judges sitting on the court of appeals concurred in the denial of plaintiffs' petition for a rehearing by the court *en banc*.

It has been held that this Court "cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional show of error." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949). The *Graver* ruling was cited with

approval in *Goodman v. Lukens Steel Co.*, 482 U.S. 656 (1987), which found:

> [t]he Court of Appeals did not set aside any of the District Court's findings of fact that are relevant to this case. That is the way the case comes to us, and both courts below having agreed on the facts, we are not inclined to examine the record for ourselves absent some extraordinary reason for undertaking this task.

Id. at 665; *see also Rogers v. Lodge*, 458 U.S. 613, 623 (1982) (noting this Court's reluctance "to disturb findings of fact concurred in by two lower courts"). No "obvious and exceptional" or "extraordinary" showing of error is present here; to the contrary, the unreliability of plaintiffs' expert testimony is fully supported by a voluminous record.

Rule 10.1 of the Rules of the Supreme Court sets forth the "character of reasons" that will be considered in determining whether to grant a writ of certiorari. Although Rule 10.1 states that its guidelines for the granting of a petition for a writ of certiorari are "neither controlling nor fully measuring the Court's discretion," it is worthy of note that the *Daubert* decision resolved all prior conflicts among the circuits, and none of the other reasons for granting a writ set forth in Rule 10.1 apply to this case. Rule 10.1, moreover, specifically requires that the granting of the writ be limited to cases where there are "special and important reasons," which are not present here.

It is respectfully submitted that the petition for writ of certiorari should be denied because the petition primarily seeks a review of the factual record, there is no

conflict among the circuits, and there are no "special and important reasons" as required by Rule 10.1 to grant plaintiffs' petition.

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be denied.

Respectfully submitted,

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